Prevalence of vitamin D defiency, its determinants and associations with health factors in infants and toddlers in the Netherlands

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vitamin related disorders
Study type	Observational invasive

Summary

ID

NL-OMON41767

Source
ToetsingOnline

Brief title
The kiDs study

Condition

- Vitamin related disorders

Synonym
'vitamin D deficiency' and 'hypovitaminosis D'

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum

Source(s) of monetary or material Support: Nutricia

Intervention

Keyword: Vitamin D status - infants - toddlers - the Netherlands

Outcome measures

Primary outcome

By capillary blood drawing followed by analysis with the Dried Blood Spot methode the 25(OH)D status will be determined. Rachitic symptoms, infectious airway diseases, growth, weight status, and motoric development will be determined by physical examination.

Secondary outcome

Recent history of infectious diseases, oral hygiene, exposure to sunlight, skin color, dietary and supplementary vitamin D will be assessed by questionnaire.

Study description

Background summary

In 2009 TNO stated the importance of an investigation on the vitamin D status in infants and toddlers in the Netherlands. In a previous investigation we showed a severe vitamin D deficiency (25(OH)D < 20 nmol/l) in 72% of neonates of non-western origin and in 24% of neonates of western origin born in a Dutch hospital. After 16 months, over 40% of these severely deficient neonates was still deficient. This is the first study investigating the vitamin D status in infants and toddlers in the Netherlands.

Study objective

We aim to measure the vitamin D status (25(OH)D) and prevalence of vitamin D deficiency in Western and non-Western infants and toddlers aged six months to four years in the Netherlands. We will assess the cross sectional association between vitamin D status and various health aspects. Also determinants of vitamin D status, such as exposure to sunlight, color of the skin, and vitamin

D intake via the diet or supplements.

Study design

Observational design. The main investigation consists of questionnaires, physical examination and capillary blood drawing. For severely vitamin D deficient children (25(OH)D < 30 nmol/l) and a matched group of children with a sufficient vitamin D status (25(OH)D > 50 nmol/l) an extended physical examination including measurement of hypotonia will be performed. Measurements will be performed from mid-July to mid-September and from mid-February to mid-April. At the end of summer 2014, a pilot will be performed in 50-100 children. These children are part of the total population.
In an amendment (18th June 2015) we request approval to measure hypotonia and the shape of the skull also in the group of children with moderate vitamin D deficiency (30-50 nmol/l). This is additional to the group of children with severe vitamin D deficiency and sufficient vitamin D status who already had these measurements.

Study burden and risks

By capillary blood drawing we draw only a micro-volume of blood. It is minimally invasive and less unpleasant than a venapunction. The risks of a well-performed capillary blood drawing is minimal.

The physical examination and capillary blood drawing will take 20 minutes at most. Also, filling out the questionnaires will take 20 minutes at most.

Contacts

Public
Meander Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- aged between 6 months and 4 years
- visiting the 'consultatiebureau' in the measurement period

Exclusion criteria

• Malabsorption by coeliakie, cystic fibrosis and inflamatory bowel disease
• Chronic liver or kidney disease
• Medication influencing vitamin D metabolism like oral glucocorticosteroïds and anticonvulsivants
• Contra-indication for drawing blood
• Impaired immunostatus, HIV/AIDS/TBC
• Osteogenesis imperfecta

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO Date:	25-08-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-01-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48007.100.14